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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/084,674	02/28/2002	Johannes Bartholomaeus	148/50986	2545

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CROWELL & MORING LLP  
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WASHINGTON, DC 20044-4300

EXAMINER
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OH, SIMON J

ART UNIT	PAPER NUMBER
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1618

MAIL DATE	DELIVERY MODE
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09/11/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/084,674	<b>Applicant(s)</b> BARTHOLOMAEUS ET AL.	
	<b>Examiner</b> Simon J. Oh	<b>Art Unit</b> 1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 19 June 2007.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1 and 3-67 is/are pending in the application.
- 4a) Of the above claim(s) 10,13,14,16,19,20,22-29,33-54 and 59-61 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,3-9,11,12,15,17,18,21,30-32,55-58 and 62-67 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

**DETAILED ACTION**

***Papers Received***

Receipt is acknowledged of the applicant's amendment, response, and petition for extension of time, all received on 19 June 2007.

***Claim Rejections - 35 USC § 112***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The rejection of Claims 1 and 3-67 under 35 U.S.C. 112, first paragraph, for enablement, is hereby withdrawn.

***Claim Rejections - 35 USC § 102***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The rejection of Claims 1, 3-5, 15, 17, 18, 21, 30-32 and 62-67 are rejected under 35 U.S.C. 102(e) as being anticipated by Burnside *et al.* (U.S. Patent No. 6,322,819)

***Claim Rejections - 35 USC § 103***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

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The rejection of Claims 1, 3-9, 11, 12, 15, 17, 18, 21, 30-32, 55-58 and 62-67 under 35 U.S.C. 103(a) as being unpatentable over Oshlack *et al.* (PCT Publication No. WO 99/01111) is maintained.

### ***Response to Arguments***

Applicant's arguments filed 19 June 2007 have been fully considered but they are not found to be persuasive.

The previous claim rejections set forth under scope of enablement and anticipation have been withdrawn.

With respect to the rejection under obviousness, the applicant argues that there is no specific teaching, suggestion or motivation to make the instantly claimed invention. However, the decision by the court in *KSR International Co. v. Teleflex Inc.* forecloses the argument that such a specific teaching, suggestion, or motivation is required to support a finding of obviousness.

It is well known to those of ordinary skill the art that drug release is influenced by various factors, such as the particular form of the pharmaceutical formulation; particle size of the active agent; the quantity of polymers designed to sustain, extend, or delay release; and solubility characteristics of the active agent. Clearly, within the pending claims, at least the use of specialized polymers to help tailor the release of the active agent is within the scope of the instant claims.

Furthermore, it is known in the art that various combinations of such materials are used in order to create a desired release profile of the active agent. In certain instances, such as for an

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enteric dosage form, the selection of such materials to be used in combination is determined in part by the solubility characteristics of those polymers, in consideration of the changing pH values throughout the gastrointestinal tract. Even polymers of the same chemical formula may be used in combination if they are of different molecular weights.

In the view of the examiner, it is well within the purview of one of ordinary skill in the art to influence the release of an active agent by using different forms of the same active agent that exhibit different solubility characteristics, just as combinations of polymers of different solubility characteristics are used to establish a desired release profile. The selection of salts of the same active agent having different solubility characteristics is a modification that is well within the skill of one of ordinary skill in the art, for the reasons described above. Therefore, the prior art rejection for obviousness is maintained.

### ***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

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however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

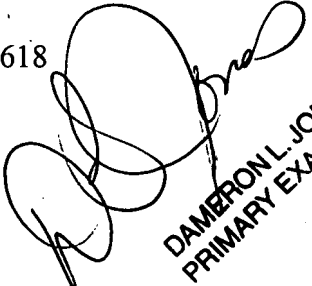
***Correspondence***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Simon J. Oh whose telephone number is (571) 272-0599. The examiner can normally be reached on M-F 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Simon J. Oh  
Examiner  
Art Unit 1618



DAMERON L. JONES  
PRIMARY EXAMINER

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